IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF SOUTH CAROLINA
FLORENCE DIVISION

GENESIS HEALTH CARE INC., Plaintiff, v. XAVIER BECERRA, as Secretary of the United States Department of Health and Human Services, CAROLE JOHNSON, as Administrator of the Health Resources and Services Administration, and EMEKA EGWIM, as Lieutenant Commander in the United States Public Health Service and Director of the Office of Pharmacy Affairs in the Health Resources and Services Administration, Defendants.	No. 4:19-cv-01531-RBH

BRIEF OF ABBVIE, INC., BRISTOL MYERS SQUIBB COMPANY, ELI LILLY & COMPANY, AND MERCK & CO, INC. AS *AMICI CURIAE* IN OPPOSITION TO PLAINTIFF'S MOTION FOR SUMMARY JUDGMENT AND IN SUPPORT OF DEFENDANTS' CROSS-MOTION FOR SUMMARY JUDGMENT

CORPORATE DISCLOSURE STATEMENT

Pursuant to Federal Rule of Civil Procedure 7.1(a), AbbVie, Inc. certifies that it has no parent corporation and no publicly held corporation owns ten percent or more of its stock.

Pursuant to Federal Rule of Civil Procedure 7.1(a), Bristol Myers Squibb Company certifies that it has no parent corporation and no publicly held corporation owns ten percent or more of its stock.

Pursuant to Federal Rule of Civil Procedure 7.1(a), Eli Lilly & Company. certifies that it has no parent corporation and no publicly held corporation owns ten percent or more of its stock.

Pursuant to Federal Rule of Civil Procedure 7.1(a), Merck & Co, Inc. certifies that it has no parent corporation and no publicly held corporation owns ten percent or more of its stock.

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INTEREST OF *AMICI CURIAE*[1]

Amici have a particular interest in this case because they participate in the 340B program and are directly affected by the extent to which covered entities, such as Genesis, unlawfully resell or otherwise transfer *amici*'s drugs at deeply discounted prices to non-patients. *Amici* are concerned that Genesis is advancing a legal theory that would limitlessly expand the 340B program and effectively nullify the statute's prohibition on drug diversion. In particular, Genesis suggests that a "patient" is any person with whom Genesis has at one time claimed to have established a relationship, no matter how attenuated. In this way, covered entities are not only acting contrary to the law as set forth in the 340B statute, 42 U.S.C. § 256b, but they are also retaining the profits for themselves rather than passing them on to their purported "patients." For this reason, the Court should take this opportunity to clarify the plain meaning of "patient" as used in 42 U.S.C. § 256b(a)(5)(B). A straightforward meaning of the term can be arrived at using ordinary tools of statutory interpretation. Without such clarification, covered entities will continue their unbridled abuse of the 340B program.

Amici are concerned that the government does not adequately represent their interests in this case. In particular, the government has chosen not to enforce the statute against Genesis, despite extensive evidence establishing that Genesis repeatedly violated the statute's requirements. While *amici* agree with the government that judgment should be granted in its favor, this brief includes additional textual arguments and valuable context not included in the government's brief that is important to understanding the nature of this dispute and the far-reaching consequences of

[1] *Amici curiae* certify that (1) this brief was authored entirely by its counsel and not by counsel for any party, in whole or in part; (2) no party or counsel for any party contributed money to fund preparing or submitting the brief; and (3) apart from amicus curiae, its members, and its counsel, no other person contributed money to fund preparing or submitting this brief.

the relief that Genesis seeks. *Amici* therefore believe that this brief may be particularly helpful to the Court in resolving this dispute.

INTRODUCTION AND SUMMARY OF ARGUMENT

Congress enacted Section 340B of the Public Health Service Act (the "340B program") to help ensure that poor and uninsured patients have better access to affordable medications. Under the statute, pharmaceutical manufacturers that participate in Medicaid are required to offer their drugs at deeply discounted prices to "covered entities"—certain hospitals and clinics that are supposed to disproportionately care for needy patients. *See* 42 U.S.C. § 256b. The statute also contains safeguards to protect against abuse and to keep the program within proper constitutional bounds, while ensuring that manufacturers have an incentive to participate in federal healthcare programs. One of the most important of those safeguards is the statute's anti-diversion provision, which prohibits a covered entity from reselling or otherwise transferring manufacturers' discounted drugs to anyone who is not a "patient of the entity." *Id.* § 256b(a)(5)(B).

In recent years, some covered entities (including Genesis) have abused the 340B program, transforming it into an arbitrage scheme for the financial benefit of themselves and their for-profit contracting partners. These abuses are well documented. *See, e.g., Program Integrity: FY22 Audit Results*, HRSA.gov (July 2023), https://www.hrsa.gov/opa/program-integrity/fy-22-audit-results; *see also* H. Energy & Commerce Comm., Review of the 340B Drug Pricing Program, at 38 (Jan. 2018) ("2018 House Report") (finding that roughly half of audited covered entities unlawfully sold or transferred 340B drugs to non-patients). In particular, instead of using the discounted 340B drugs to help their needy patients afford medications, these covered entities sell the drugs at full market prices to wealthy and fully insured individuals and then pocket the profits (the "spread") for themselves. What was envisioned as a cost-reduction program has morphed into an engine for covered entities' profit (which they euphemistically refer to as "savings"). Moreover, to increase

the opportunities they have to generate "spread," some covered entities have entered contractual relationships with commercial pharmacies across the country and have claimed that the pharmacies' customers qualify as their own "patients," no matter how attenuated the relationship might be between the customers and the covered entities themselves. Indeed, there are instances where multiple covered entities each claim the same patient as their own—and each claim a 340B discount—for a *single* prescription.

The 340B statute's prohibition on diverting 340B drugs to non-patients bars the resale or transfer of discounted 340B drugs to anyone who is not a patient of the covered entity itself. *See* 42 U.S.C. § 256b(a)(5)(B). Under the statute, there must be a nexus between the individual who receives a 340B drug, the specific healthcare services for which the drug is dispensed, and the covered entity that is accessing the drug at the discounted price in connection with the specific healthcare services provided to the individual. The statutory phrase "patient of the entity" thus refers to an individual (1) currently receiving care from a physician acting on behalf of the covered entity, (2) under an established and ongoing patient-physician relationship, and (3) who receives the 340B prescription from the physician in connection with the healthcare the entity is itself providing. This definition not only tracks the plain meaning of "patient" but also fits within the 340B statute's context, structure, and other requirements. Unfortunately, the Health Resources and Services Administration ("HRSA") has largely failed to enforce the statute's diversion prohibition. Instead, the agency has allowed covered entities to abuse the program, at great cost to manufacturers and the needy patients the 340B program is supposed to benefit.

This case is a rare instance in which HRSA chose, at least initially, to bring an enforcement action against a covered entity—Genesis—for violations of the 340B statute. After directing an audit, HRSA found that Genesis failed to maintain auditable records and "systematically"

dispensed 340B drugs to ineligible individuals. To avoid any consequences for its actions, however, Genesis urges the Court to adopt an indeterminate and overbroad definition of the term "patient." Genesis contends that any pharmacy customer qualifies as its "patient" for 340B purposes as long as Genesis and the customer can claim a relationship because they have previously had some "encounter," even if the drug dispensed to the individual has no connection with any healthcare service provided by the Genesis itself. Genesis's overbroad definition includes customers with a prescription from another provider or customers who may receive the bulk—even all—of their care at other institutions. It also includes prescriptions written by physicians providing care at other healthcare providers. On this score, Genesis's math is as simple as it is cynical: the broader the definition of "patient," the greater the number of individuals it can use to extract arbitrage profits.

This proposed definition is defective for at least four reasons. ***First***, such a broad definition is without content, sweeping in anyone that has ever had any encounter with Genesis—no matter how remote in time or attenuated to the prescription it might be. ***Second***, it would permit Genesis to dispense 340B drugs to individuals in situations where the drugs bear no relationship to the healthcare that Genesis may have provided. ***Third***, and as a result, the receipt of 340B drugs becomes a matter of mere coincidence: it is not the poor and uninsured who receive discounted drugs in connection with a service Genesis is providing as a covered entity, but anybody—regardless of their ability to pay—who happens to have at one time previously had some encounter with Genesis. ***Fourth***, Genesis's definition creates a serious risk—one that has already borne out—that multiple entities will claim and enjoy a discount on the same drug provided to the same patient.

Consider a woman taken to Genesis for an earache as an infant, who in elementary school is treated for a broken arm at an unrelated hospital, who much later in life gives birth in a third hospital, and who ultimately receives cancer treatment at another institution in her old age. Under Genesis's once-a-patient, always-a-patient definition, Genesis and *each* of the three hospitals, if they are covered entities, could claim that woman as their "patient," and claim to be entitled to obtain 340B profits based on a prescription provided to her during the course of her cancer treatment.

In Genesis's view, nothing stops it from diverting drugs to a commercial pharmacy's customers without regard to whether those customers are receiving the drugs in connection with healthcare services Genesis is providing. That Genesis will exploit this expansive definition to increase its arbitrage profits is not speculative: evidence shows that Genesis has violated its statutory obligations by failing to maintain auditable records and by repeatedly reselling or otherwise transferring manufacturers' discounted drugs to customers of third-party pharmacies who, under any reasonable understanding of the term, do not qualify as Genesis's "patients." There is thus no reason to think that Genesis is dispensing the 340B drugs in a way that benefits its poor and uninsured patients. Rather than grant Genesis a blank check, the Court should reject Genesis's position as contrary to the proper definition of "patient." It should rule against Genesis and grant summary judgment in the government's favor.

ARGUMENT

Conceived as a statute to help low-income and uninsured patients by requiring pharmaceutical manufacturers to offer outpatient drugs at deeply discounted prices to certain health care organizations (known as covered entities), which are supposed to care for large numbers of uninsured and low-income patients, the 340B program has become a scheme for covered entities to extract arbitrage profits on 340B drugs at the expense of manufacturers and

patients, particularly in underserved communities. HRSA has concluded that Genesis is one such entity. But rather than reform its behavior, Genesis asks this Court to revolutionize the outpatient drug market by ruling that Genesis may sell 340B drugs to anyone it has ever encountered. That request conflicts with the plain meaning of "patient" and would distort Congress's well-calibrated scheme.

I. Preventing Covered Entities from Reselling or Otherwise Transferring Discounted Drugs to Non-Patients Is Essential to Protecting the 340B Program's Integrity.

Congress designed the 340B statute to help ensure that poor and uninsured patients would benefit from deep discounts on the medications they need. Genesis has abused the program by selling discounted drugs at market prices to pharmacy customers who are not its patients in any ordinary sense of the word.

A. Congress Designed the 340B Statute with the Expectation That Discounted Drugs Would Be Used for the Benefit of Poor and Uninsured Patients.

Before 1992, manufacturers voluntarily supplied their drugs at reduced prices to entities that provided healthcare services to underprivileged patients. The creation of the federal Medicaid Drug Rebate Program, however, created a substantial "disincentive" for manufacturers to continue voluntarily providing discounts to those entities. *See* H.R. Rep. No. 102-384, pt. 2, at 9-10 (1992). Manufacturers that provided even a single unit of discounted drugs to charitable hospitals could face dramatic increases in their Medicaid rebate liability. *See* Nicholas C. Fisher, *The 340B Program: A Federal Program in Desperate Need of Revision After Two-and-a-Half Decades of Uncertainty*, 22 J. Health Care L. & Pol'y 25, 30, 41-42 (2019). Congress responded in 1992 by eliminating the "disincentive" in the Medicaid law and by enacting the 340B statute to make the voluntary discounts mandatory. The 340B statute requires that, as a condition of participating in the Medicaid program, drug manufacturers must offer their drugs at discounted prices to certain qualifying hospitals and clinics—referred to as "covered entities." 42 U.S.C. § 256b; *Astra USA,*

Inc. v. Santa Clara Cnty., 563 U.S. 110, 113 (2011). The significant discounts mandated by the statute range from a minimum of 23.1% of a branded drug's cost to essentially 100% off (a penny per pill), depending on many factors. *See* 42 U.S.C. § 1396r-8(c).

Congress intended that covered entities would use the discounted drugs for the benefit of the uninsured and poor patients who visit their facilities for medical services and care. *See* H.R. Rep. No. 102-384, pt. 2, at 7 (noting that the bill's purpose was "to enable … certain Federally-funded clinics to obtain lower prices on the drugs that they provide to their patients"). As the government has recognized, Congress designed the statute with the expectation that covered entities would "pass all or significant part of the discount to their patients." HRSA, *Notice Regarding Section 602 of the Veterans Health Care Act of 1992; Contract Pharmacy Services*, 61 Fed. Reg. 43,549, 43,551 (Aug. 23, 1996). The statute is not designed to create a profit-making opportunity for covered entities or the for-profit pharmacies with which they contract. *See AstraZeneca Pharms. LP v. Becerra*, 543 F. Supp. 3d 47, 60 (D. Del. 2021) ("It is hard to believe that Congress enumerated 15 types of covered entities with a high degree of precision and intended to include contract pharmacies as a 16th option by implication."), *aff'd sub nom. Sanofi Aventis U.S. LLC v. HHS*, 58 F.4th 696, 703 (3d Cir. 2023).[2]

[2] Contrary to the government's suggestion, there is no reason that the interests of manufacturers and covered entities should be in tension as long as the statute is properly enforced. *Cf.* Dkt. 101 at 4. Manufacturers have not sought to limit the "volume of 340B discounts" when the discounted drugs are given to and used to treat uninsured and low-income patients. In fact, as noted above, the 340B program emerged out of the previously voluntary discounts that manufacturers supplied to non-profit providers. What manufacturers object to is allowing the 340B program to be transformed into a boundless arbitrage scheme used for the financial profit of covered entities and third-party commercial entities at the expense of needy patients. The drugs belong to manufacturers; covered entities (and their commercial contracting partners) have no rights to access those drugs except as provided in the 340B statute. *See Astra*, 563 U.S. at 113 (recognizing that covered entities have no right to enforce the statute).

Ensuring that the discounted drugs under the 340B program are used for the benefit of poor and uninsured patients is necessary to avoid serious constitutional concerns. Under our Constitution, the government has no authority to force A-to-B transfers of private property for the benefit of private parties. *See Kelo v. City of New London*, 545 U.S. 469, 477 (2005) (explaining that "the sovereign may not take the property of *A* for the sole purpose of transferring it to another private party *B*, even though *A* is paid just compensation"). Accordingly, Congress has no lawful power to force manufacturers to transfer their drugs to hospitals and other covered entities for their own private benefit (or the financial benefit of their commercial contracting partners). *Cf. Horne v. Dep't of Agric.*, 576 U.S. 350, 370 (2015) (holding that government lacks authority to confiscate portion of farmers' raisin crop for charitable and other purposes). Nor does the government have authority to pressure manufacturers to relinquish their constitutional rights as a condition of participating in government programs. *See id*. at 365-66. Although the government may "require property owners to cede" certain of their property rights as "a condition of receiving certain benefits" under a federal program, it can do so only if the condition bears an "essential nexus" and "rough proportionality" to a legitimate governmental interest. *Cedar Point Nursery v. Hassid*, 141 S. Ct. 2063, 2079 (2021) (quoting *Dolan v. City of Tigard*, 512 U.S. 374, 386, 391 (1994)); *see also Horne*, 576 U.S. at 366 (explaining that selling products in interstate commerce is not a "special … benefit" the government "may hold hostage, to be ransomed by the waiver of constitutional protection").

Congress was thus obliged to structure the 340B statute to ensure an "essential nexus" and "rough proportionality" between the statute's requirements and its only valid purpose—helping poor and uninsured patients gain access to discounted drugs in connection with healthcare services provided to them by covered entities. More specifically, Congress included safeguards in the

statute to limit which entities could benefit from accessing manufacturers' drugs at deeply discounted prices. The statute defines with precision which entities qualify as "covered entities." 42 U.S.C. § 256b(a)(1), (a)(4)(A)–(O) (listing 15 categories of clinics, non-profit hospitals, and other safety-net providers). It restricts HHS's substantive rulemaking authority, denying the agency power to expand the program's reach. *See Pharm. Rsch. & Mfrs. of Am. v. HHS*, 43 F. Supp. 3d 28, 41 (D.D.C. 2014). And, most relevant here, the statute prohibits any covered entity from "resell[ing] or otherwise transferr[ing]" manufacturers' drugs "to a person who is not a patient of the [covered] entity." 42 U.S.C. § 256b(a)(5)(B).

That strict prohibition—known as the anti-diversion provision—is a fundamental feature of the 340B program. It is designed to ensure that covered entities use manufacturers' discounted drugs only for the benefit of those individuals who obtain the drugs in connection with healthcare services provided by the covered entity itself. Without the anti-diversion provision, the "essential nexus" that forms the constitutional foundation for the program would be undone. The provision also provides a two-fold protection to program participants: on one hand, it prevents covered entities from exploiting discounts in a way that could drive manufacturers out of the Medicaid program; on the other, it helps to ensure that the 340B program is used for the benefit of needy patients and not simply to allow covered entities and for-profit pharmacies to make windfall profits by reselling discounted drugs at regular (non-discounted) prices to non-patients and pocketing the difference. Underscoring the importance of this provision, Congress in 2010 directed the Secretary of Health and Human Services to implement improvements necessary to ensure compliance by covered entities with the statute's diversion prohibition. *See id.* § 256b(d)(2)(A). It also authorized the Secretary and drug manufacturers to enforce the diversion clause through audits of

the covered entity's "records" and through administrative adjudications overseen by HRSA. *See id*. § 256b(a)(5)(C)–(D).

B. Covered Entities Have Abused the 340B Program for Their Own Financial Gain by Selling and Transferring Discounted Drugs to Non-Patients.

The 340B program has grown at an astounding pace, becoming the nation's second-largest prescription drug program, larger even than the Medicaid Drug Rebate Program to which 340B is supposed to be an adjunct. *See* Aaron Vandervelde & Andrew Brownlee, Revisiting the Pharmaceutical Supply Chain: 2013-2018 (2020). HRSA's records suggest that discounted purchases under the 340B program reached $44 billion in 2021. *See 2021 340B Covered Entity Purchases*, HRSA.gov (Aug. 2022). And total 340B sales have continued to grow in 2023 at a 4.5% greater pace than the drug market as a whole. *See* Rory Martin, White Paper: The 340B Drug Discount Program Exceeds $100B in 2022, at 3 (IQVIA Mkt. Access Ctr. of Excellence 2023). To put those figures in perspective, from 2007 to 2009, the estimated purchases under the 340B program totaled approximately only $4 billion per year—that means the program ballooned by 1100% in just over a decade. *See* Karen Mulligan, White Paper: The 340B Drug Pricing Program: Background, Ongoing Challenges and Recent Developments, at 4 (Univ. S. Cal. Schaeffer Ctr. for Health Pol'y & Econ. 2021).

The program's explosive growth has not resulted from an increase in the number of indigent patients served or improvements in care by covered entities provided to those patients. Between 2010 and 2020, the percentage of uninsured patients in the United States fell by 38%. *See* Kenneth Finegold et al., HHS APSE Office of Health Policy, No. HP-2021-02, Trends in the U.S. Uninsured Population, 2010–2020 (Feb. 1, 2021). Moreover, studies show that expansions in the 340B program have been accompanied by a *reduction* in the amount of charity care delivered by covered entities. *See* Wayne Winegarden, PRI Ctr. for Med. Econ. & Innovation, Profiting

from 340B: A Review of Charity Care and Financial Performance at 340B Hospitals, at 7 (2021); Adam J. Fein, *Exclusive: 340B Program Purchases Reach $24.3 Billion—7% of the Pharma Market—As Hospitals' Charity Care Flatlines*, Drug Channels (May 14, 2019); *see also* Gov't Accountability Office ("GAO"), No. GAO-23-106095, 340B Drug Discount Program: Information About Hospitals that Received an Eligibility Exception as a Result of Covid-19 (May 2023) (nearly half of 340B hospitals fail to provide discounts to low-income uninsured patients at contract pharmacies); William Smith & Josh Archambault, *340B Drug Discounts: An Increasingly Dysfunctional Federal Program*, at 5 (Pioneer Inst. Pub. Pol'y Rsch. White Paper No. 248, 2022), https://bit.ly/3MShVog (explaining the evidence that "as 340B revenue has expanded exponentially, services provided to vulnerable populations have declined").

The dramatic increase in the size of the 340B program begins to make sense when one considers the growth of for-profit participation: covered entities and commercial contract pharmacies are able to extract profits by selling manufacturers' discounted drugs at regular (non-discounted) prices to individuals (non-patients) who are not purchasing the drugs in connection with healthcare services provided by the covered entity itself. *See* GAO, No. GAO-20-212, 340B Drug Discount Program: Oversight of the Intersection with the Medicaid Drug Rebate Program Needs Improvement, at 2 (Jan. 2020). As commentators have noted, "[w]hat started as a well-intentioned effort to provide safety-net providers free or discounted drugs to treat uninsured and vulnerable patients appears to have evolved into a profit-centric corporate initiative that has fundamentally altered the 340B program." Aaron Vandervelde, Kevin Erb & Lauren Hurley, For-Profit Pharmacy Participation in the 340B Program, at 3 (Oct. 2020). "For a while, the [340B] program worked as intended…. But over time, [hospital] greed has cropped up and made a mockery of the program, resulting in practices that furthers health inequities in our nation."

Benjamin F. Chavis, *Safeguarding Charitable Medicine Programs in America*, Wash. Informer (July 13, 2023).

Indeed, as 340B participants realized this arbitrage opportunity, contract pharmacy participation exploded by 4,228% from April 2010 to April 2020. *See* Vandervelde, For-Profit Pharmacy Participation, *supra*, at 3. And HRSA recently published findings showing that nearly half—and in some years more than half—of audited covered entities unlawfully sold or transferred 340B drugs to non-patients. *See Program Integrity: FY22 Audit Results*, HRSA.gov, *supra*; *see* 2018 House Report at 38. Further, both the *New York Times* and the *Wall Street Journal* have published detailed reports describing abuses of the 340B program that have allowed for large-scale fraud and damage to the vulnerable patient communities that Congress designed the 340B program to help. *See* Katie Thomas & Jessica Silver-Greenberg, *Profits Over Patients: How a Hospital Chain Used a Poor Neighborhood to Turn Huge Profits*, N.Y. Times (Sept. 24, 2022); Anne Wilde Mathews et al., *Many Hospitals Get Big Drug Discounts. That Doesn't Mean Markdowns for Patients*, Wall St. J. (Dec. 20, 2022); Sarah Kliff & Jessica Silver-Greenberg, *This Nonprofit Health System Cuts Off Patients With Medical Debt*, N.Y. Times (June 1, 2023) ("Doctors at the Allina Health System, a wealthy nonprofit in the Midwest, aren't allowed to see poor patients or children with too many unpaid medical bills.").

Evidence shows that many of the 340B program's abuses have resulted from deliberate reselling or transferring of drugs to individuals (and entities) who are not patients. As the Government Accountability Office has explained, some covered entities "broadly interpret[] the definition [of patient] to include individuals such as those seen by providers who are only loosely affiliated with a covered entity and thus, for whom the entity is serving an administrative function and does not actually have the responsibility for care." GAO, No. GAO-11-836, Drug Pricing:

Manufacturer Discounts in the 340B Program Offer Benefits, but Federal Oversight Needs Improvement, at 22-23 (Sept. 2011). Presentations by consultants seeking to exploit the program's expansion by identifying novel arbitrage opportunities have encouraged covered entities to treat as "patients" individuals whom HRSA has identified as diversion risks, such as "covered entity employees who do not receive healthcare services from the entity, and thus do not qualify as patients." Biotechnology Indus. Org. et al., The 340B Drug Discount Program: A Review and Analysis of the 340B Program, at 18 (2013) (describing a slide presentation). Consultants have also focused on a covered entity's "ability to generate revenue" by selling manufacturers' drugs to "government-funded populations," including "prisoners," and treating them as patients. *Id*. at 18 & n.85 (quotation marks omitted); *see also Use Your Hospital's Retail Pharmacy 340B Drug Savings To Build A Specialty Pharmacy*, ProxsyxRx.com (Sept. 12, 2022) (describing how a third party "pay[s] [it]self" from a covered entity's 340B margin). And consultants have advised covered entities to take an unlawful "once-a-patient, always-a-patient" approach, providing drugs acquired at discounted prices to individuals who at one time visited the covered entity but have since received their healthcare services and prescriptions from somewhere else. *See* Rob Nahoopii & Riley Protz, *Simplifying Your Referral Capture Solution*, SpendMend.com (June 28, 2022), https://www.spendmend.com/portfolio/simplifying-your-referral-capture-solution/ (advising covered entities to capture 340B revenue for non-patients who receive "all follow up care and prescriptions provided and written at private practice"); *340B Insider: an interactive Q&A session with 340B experts*, at 14:00-16:00, cloudmed.com (2023) (lawyer for covered entities proposing "say[ing] everybody we've ever treated at any point is our patient and they're eligible for 340B drugs").

The failure of covered entities, including Genesis, to maintain adequate records has made it difficult to address rampant diversion, even though the statute imposes that record-keeping obligation on them. *See* 42 U.S.C. § 256b(a)(5)(C). Increased use of contract pharmacies has exacerbated the problem. Commercial pharmacies do not possess and do not have access to the records of the covered entity's patients and, therefore, cannot determine at the time of sale whether the person seeking to fill a script is a "patient" for 340B purposes. *See Examining Oversight Reports on the 340B Drug Pricing Program: Hearing Before the S. Comm. on Health, Educ., Lab., & Pensions*, 115th Cong. 11 (May 15, 2018) (statement of Ann Maxwell, Assistant Inspector Gen. (OIG)) ("Retail contract pharmacies often have no way to distinguish a 340B patient from any other customer filling a prescription at their stores."); *see also Examining HRSA's Oversight of the 340B Drug Pricing Program: Hearing Before the Subcomm. on Oversight & Investigations of H. Comm on Energy & Com.*, 115th Cong. (July 18, 2017) (statement of Erin Bliss, Assistant Inspector Gen., HHS).

Most often, covered entities and contract pharmacies effectuate this diversion by using the "replenishment" inventory model, a fiction invented and used exclusively in the 340B program to expand and capture arbitrage profits: covered entities and contract pharmacies work together to create a fictional regime in which covered entities claim that they purchase drugs, even though the drugs are controlled by contract pharmacies and dispensed without regard to whether an individual is a covered entity's patient. Specifically, when a contract pharmacy is running low on a given drug, the pharmacy (or an affiliate, but not the covered entity) uses a covered entity's account to order more of the drugs at the 340B price from the manufacturer; the pharmacy asks for delivery to be made directly to it (not to the covered entity); and, once the shipment arrives, the pharmacy merges the discounted drugs into its general inventory. Covered entities do not take—and certainly

do not "maintain"—title to the drugs. *See Notice Regarding 340B Drug Pricing Program-Contract Pharmacy Services*, 75 Fed. Reg. 10,272, 10,277 (Mar. 5, 2010). Instead, when a pharmacy customer fills a prescription, the customer is charged the full price by the pharmacy and receives the drug out of the pharmacy's general inventory without any attempt by the pharmacy to identify whether the customer is a 340B-eligible patient of a particular covered entity. Then, as the government has acknowledged elsewhere, the pharmacy uses manipulable, undisclosed algorithms weeks later to estimate how many of those customers might be deemed 340B "patients" based on some attenuated relationship to a covered entity (or even multiple covered entities). The contract pharmacy then uses the results of the algorithms to justify orders of 340B discounted drugs that the contract pharmacy has shipped to itself using the covered entity's account. *See AstraZeneca Pharms. LP*, 543 F. Supp. 3d at 61 n.19; HHS-OIG Memorandum Report: Contract Pharmacy Arrangements in the 340B Program, No. OEI-05-13-00431, at 2-5 (Feb. 4, 2014), https://bit.ly/3eWKmBQ; Aharon Gal, Examining Hospital Price Transparency, Drug Profits, and the 340B Program, at 4, 14-15 (Sept. 2021), https://bit.ly/3yvdko4.

Through this scheme, the covered entity and the pharmacy share in the "spread" generated by selling the 340B drugs to the pharmacy customers at regular prices and pocketing the profits for their own benefit. The pharmacy's customers (and their health plans) pay the regular price for the drugs and never see the deep discounts provided by manufacturers. The customers are deemed "patients" of a covered entity even though the covered entity itself had nothing to do with the particular health care services that resulted in the customer's prescription. And, instead of helping poor and uninsured patients, the 340B program is transformed into a profit-making scheme.

C. Genesis Has Unlawfully Transferred Drugs to Non-Patients.

Genesis has been widely and rightly criticized for diversion and abuse, as the government's brief documents in detail. *See* Dkt. 101 at 5-9. In 2021, Genesis is estimated to have made a $19

million surplus on $52 million in revenue—a margin of 37 percent—as a result of purchasing and reselling 340B discounted drugs. That was the fourth consecutive year Genesis's surpluses topped 35%, even though the industry average is approximately 5%. *See* Phil Galewitz & Bram Sable-Smith, *For a few community health centers, serving the poor brings big surpluses*, Wash. Post (Aug. 12, 2022). HRSA's audit found that Genesis did not maintain auditable records sufficient to show that the individuals to whom it resold discounted drugs were actually Genesis's patients, as the statute requires. *See* Dkt. 1, Ex. 1 (Final Report) at 6-8. Many of the pharmacies that Genesis has contracted with were found to have provided prescriptions to non-patients but treated those customers as 340B eligible. *Id.* at 9-10.

Moreover, Genesis was unable to demonstrate that the individuals who received manufacturers' drugs received healthcare services from Genesis itself by a healthcare professional employed by Genesis. Instead, Genesis "set up a process that systemically allowed the in-house pharmacy to dispense 340B drugs to ineligible" individuals. *Id.* at 10. Genesis's own policies indicated that it would dispense a 340B drug to an individual as long as Genesis could find or generate a medical record for that individual within the past two years—even if the prescription was unrelated to any healthcare services provided by Genesis. *Id*.

Against this backdrop, it is important to recognize the extremely disruptive consequences that would result from Genesis's bid to drain the 340B statute's anti-diversion provision of any meaning. To avoid such a sweeping disruption to the outpatient drug market, the Court should take this opportunity to clarify the proper definition of "patient" in § 256b(a)(5)(B).

II. The Proper Meaning of "Patient" Requires Ruling Against Genesis on the Merits.

This case comes down to the meaning of the phrase "patient of the entity" as used in 340B's anti-diversion provision. That provision instructs that "a covered entity shall not resell or otherwise transfer [any covered outpatient drug] to a person who is not a patient of the entity." 42

U.S.C. § 256b(a)(5)(B). Genesis asks this Court to declare that the term "patient" merely requires *some* past "encounter" with the covered entity—no matter how far in the past—and that such an individual may come to Genesis or one of its contract pharmacies to fill "any prescription from any source," all of which Genesis can then replenish, unbeknownst to the individual, at a steep 340B discount. Dkt. 33 ¶¶ 65-66, 68-69. If Genesis is wrong that "patient" status does not require anything more than some ill-defined relationship with the entity, then its requests for relief must be denied. And indeed, that definition is incorrect as a matter of law—both because it conflicts with the plain meaning of "patient" and because it would drain the statute's anti-diversion provision of any meaning, violating bedrock principles of statutory construction.

As used in the statute and in light of the statute's requirements and structure, a "patient" of a covered entity is an individual who is receiving a 340B drug in connection with healthcare services provided by the covered entity itself. More specifically, the phrase "patient of the entity" refers to an individual who, at a minimum, (1) is currently receiving care from a physician providing services at a covered entity, (2) with an established and ongoing physician-patient relationship, and (3) has received the prescription for the 340B drug from the physician while acting on the covered entity's behalf, in connection with the services the physician is providing. As explained below, this straightforward understanding is consistent with both the ordinary meaning of the term and the broader 340B statutory scheme.

Congress's words should be interpreted "consistent with their 'ordinary meaning … at the time Congress enacted the statute.'" *Wis. Cent. Ltd. v. United States*, 138 S. Ct. 2067, 2070 (2018) (quoting *Perrin v. United States*, 444 U.S. 37, 42 (1979)). That basic canon requires construing the word "patient" to refer to a person with a *present* relationship with a particular physician. The *Oxford English Dictionary* defines patient to mean "[a] person *receiving* or … registered to receive

medical treatment," especially "at a particular establishment or from a particular practitioner…." Oxford English Dictionary (3d ed. 2015) (emphasis added); *see also* Oxford Advanced Learner's Dictionary __ (10th ed. 2020) (defining "patient" to mean "a person who *is* receiving medical treatment, especially in a hospital," and "a person who *receives* treatment from a particular doctor, dentist, etc." (emphasis added)). Similarly, the edition of *Black's Law Dictionary* that was published around the time of section 340B's enactment defines "patient" to mean a "[p]erson under medical or psychiatric treatment and care." Black's Law Dictionary (6th ed. 1990). The plain meaning of "patient," then, requires at least two things: (1) the person must be *currently receiving treatment*, and (2) the person's status as a patient is tied to a *particular healthcare provider*, who is acting within the scope of their affiliation with a covered entity.

Other features of the statute reinforce these established definitions. Section 340B is written in the present tense: It provides that a qualifying individual "is" a patient of a covered entity—not "was" or "once used to be" a patient. *See* 42 U.S.C. § 256b(a)(5)(B). If an individual's last encounter with a physician was a yearly physical in 2001—or worse, when the individual was born in 1993—the physician would not refer to the individual as "my patient" today, any more than an individual would refer to the physician as "my doctor." The proper usage of "patient" recognizes this temporal element.

The same is true of the need to tie patient status for a particular prescription to a particular service received from a particular healthcare provider. Consider an individual who receives care from both an orthopedic surgeon and a primary-care physician; she is the surgeon's patient for purposes of her post-operation care and prescriptions, but she is the primary-care physician's patient for purposes of general care, such as cholesterol control. No speaker of English would say the individual "is a patient" of the orthopedic surgeon when receiving her cholesterol medication.

The individual's status as a patient is tied to the prescribing physician and the purposes for which she is receiving that physician's care.

The statute's definition of "covered drug" also supports this interpretation. Recall that the diversion provision does not address all drugs, but only "covered outpatient drugs"—*i.e.*, 340B drugs. Specifically, the statute says: "With respect to any covered outpatient drug" subject to 340B pricing, "a covered entity shall not resell or otherwise transfer the drug to a person who is not a patient of the entity." 42 U.S.C. § 256b(a)(5)(B). The statute then defines "covered drug" to mean any "covered outpatient drug" as defined in the Social Security Act *and* "a drug used *in connection with* an … outpatient service *provided by a hospital* … that is enrolled to participate in the drug discount program under this section." *Id.* § 256b(b)(2)(B) (emphasis added). Necessarily, then, "covered drugs" must be used in connection with a specific episode of outpatient healthcare that the covered entity itself is providing. These provisions underscore Congress's intent that covered entities dispense 340B drugs to individuals only when the drugs are used in connection with healthcare that the covered entity originated and is currently providing to the individual, such that the covered entity maintains responsibility for that aspect of that person's care.

And this definition furthers the 340B statute's purpose of increasing accessibility to outpatient drugs for the indigent and uninsured. The statute's fundamental aim is not to transfer wealth from manufacturers to covered entities (or worse, for-profit companies they contract with), but to reduce the costs of drugs for those in need. By tying the definition of "patient" to the services that covered entities are providing, the distribution of 340B drugs is likewise tied to expanding access to the vulnerable populations that covered entities are supposed to serve. And an interpretation that honors a statute's purpose, rather than obscures it, should be favored. *See United States v. Bryant*, 996 F.3d 1243, 1256 (11th Cir. 2021) ("As between two competing

interpretations, we must favor the 'textually permissible interpretation that furthers rather than obstructs' the statute's purposes." (quoting Antonin Scalia & Bryan A. Garner, Reading Law: The Interpretation of Legal Texts § 4, at 63 (2012))).

In Genesis's view, any attempt to provide content to the definition of patient imposes obligations beyond what Congress intended. *See* Dkt. 33 ¶ 30. Genesis would rather have a definition of "patient" that is completely circular. *See id.* ¶¶ 65, 68 (arguing that "patient of the entity" means "patient of a covered entity"); *see also* Dkt. 100-1 at 8-9 (arguing that "patient" as used in § 256b "only requires the existence of a patient relationship"). But a circular definition is no definition at all—and the Court will not impermissibly "narrow" the term by merely identifying its ordinary meaning. Indeed, every application of a text to the circumstances of a case requires interpretation: "Those who apply the rule to particular cases must of necessity expound and interpret that rule." *Marbury v. Madison*, 5 U.S. (1 Cranch) 137, 177 (1803). If Genesis is right, every act of interpretation that goes beyond merely parroting the statute could be mischaracterized as narrowing the statute. But courts have always applied interpretive rules to draw "crisper and more detailed lines" than what a casual reading of a statute might suggest. *POET Biorefining, LLC v. EPA*, 970 F.3d 392, 408 (D.C. Cir. 2020) (quoting *Am. Mining Cong. v. Mine Safety & Health Admin.*, 995 F.2d 1106, 1112 (D.C. Cir. 1993)).

Genesis's reliance on *Sanofi Aventis U.S., LLC v. U.S. Department of Health & Human Services*, 58 F.4th 696 (3d Cir. 2023), is similarly mistaken.[3] That case concerned whether drug

[3] The government says that it disagrees with the Third Circuit's holding, but it did not seek rehearing or file a petition for certiorari. The decision is therefore binding on the government. In any event, as the government explains, *Sanofi* is readily distinguished because there, the government was attempting to impose an additional obligation on manufacturers that did not exist in the statute. Here, the government is not creating new extra-statutory obligations; it is merely applying a proper interpretation of the phrase "patient of the entity."

manufacturers violated § 256b(a)(1)'s requirement to "offer" 340B drugs to covered entities when they limited the number of contract pharmacies to which they would deliver the drugs. *See id.* at 701, 703-04. The Court looked to the plain meaning of "offer" to conclude that a manufacturer still "offers" 340B drugs to a covered entity even if it will only deliver them to one of the covered entity's contract-pharmacy affiliates, rather than many. *See id.* at 703 ("Even if drug makers limit where they will deliver drugs, they still present the drugs for covered entities' acceptance.").

Sanofi provides no support for Genesis's position and, if anything, shows why Genesis is wrong. Like Genesis here, the government argued in *Sanofi* that manufacturers were impermissibly failing to comply with the statute's "must offer" obligation in refusing to deliver their drugs to third parties. The Third Circuit, relying on accepted dictionary definitions, rejected the government's position and applied the plain meaning of the term "offer" to conclude that the statute did not impose any additional third-party delivery obligation. This Court should take the same approach here and interpret the statute as Congress intended. This Court would not create any tension with *Sanofi* if, in contrast to Genesis's position, it affirmed that "patient" does have a concrete meaning that limits the individuals to whom covered entities may sell or transfer 340B drugs. It is no surprise that different words with different meanings carry distinct legal consequences.

III. Genesis Is Not Entitled to the Relief It Seeks.

Even if the Court does not follow the statutory interpretation of "patient" set forth above, it should still enter summary judgment against Genesis because, at a minimum, Genesis's "patient" definition is wrong as a matter of law.

A. The Definition Genesis Proposes Is Wrong as a Matter of Law.

The bottom-line goal of Genesis's amended complaint is to obtain a definition of "patient" so broad as to render the term meaningless. The reason is clear: if "patient" does not have any real

meaning, then it imposes no limit on the individuals upon whose backs Genesis can generate 340B profits. And without such a limit, Genesis can further expand its arbitrage profits at the expense of manufacturers and patients. To that end, Genesis asks this Court to declare that "patient" means "the person be a patient of a covered entity" and that "any prescription from any source is available to a patient of a covered entity." Dkt. 33 ¶¶ 65-66, 68-69. That is better described as a declaration that the term has no meaning, and that the anti-diversion provision has no consequence. Genesis's proposed definition suffers from four principal defects.

First, Genesis's definition is implausibly broad. It would sweep in any person who has *ever* had an encounter with Genesis, encompassing all persons with a prescription from any entity—even if Genesis does not maintain records of the person's health care, even if the person does not receive health care services from a professional employed at or under contract with Genesis, even if Genesis does not maintain responsibility for the individual's care, and even if the person does not receive a service from Genesis consistent with the purpose for which federally-qualified health center status has been awarded to Genesis. In this way, Genesis's definition places no limits on the individuals who might be deemed a "patient." A person who received treatment at Genesis for a sprained ankle in 2000 could obtain their cholesterol medication at Genesis—in 2023—and Genesis could profit from that transaction by seeking to claim it is eligible for 340B-discounted price—even if the cholesterol medication is prescribed by a treating physician who has no relationship with Genesis. It is not even clear that Genesis's definition excludes persons with no prior relationship with it but who obtain their prescriptions, which originated with another entity, through Genesis's onsite or contract pharmacies. There does not appear to be any outer boundary.

Genesis's expansive definition runs afoul of "the 'cardinal principle of statutory construction'" that courts must "'give effect, if possible, to every clause and word of a statute.'" *Bennett v. Spear*, 520 U.S. 154, 173 (1997) (quoting *United States v. Menasche*, 348 U.S. 528, 538-39 (1955)). Courts are right to reject an interpretation of a statute "that would render an entire subparagraph meaningless." *Nat'l Ass'n of Mfrs. v. Dep't of Def.*, 138 S. Ct. 617, 632 (2018). Here, the statute's anti-diversion provision is meant to prevent covered entities from exploiting the 340B program. Yet Genesis's reading removes it from the statute. The provision has little consequence if "patient of the entity," 42 U.S.C. § 256b(a)(5)(B), means all persons who have ever had an encounter with the covered entity. That makes Genesis's interpretation a non-starter. *See* Antonin Scalia & Bryan A. Garner, Reading Law: The Interpretation of Legal Texts § 26, at 174 (2012) (explaining that "every word and every provision is to be given effect").

Second, Genesis's definition divorces its distribution of 340B drugs from the services that it is providing. As a result, it retains no nexus between the services that Genesis provides to the indigent and uninsured—the very services for which Genesis enjoys its status as a federally-qualified health center (and thus a covered entity)—and the 340B drugs that Genesis is reselling to all persons, irrespective of their ability to pay. *See* 42 U.S.C. § 256b(a)(4)(A). This expansive definition thus undermines the 340B program's essential purpose of supporting the indigent and uninsured, raising serious constitutional concerns that would allow Genesis to take advantage of the statute as a take-and-transfer scheme for its own private benefit. *See* H.R. Rep. No. 102-384, pt. 2, at 12. Rather than focusing on care for the needy, such a broad definition reorients 340B into a profit vehicle for covered entities like Genesis. Indeed, 340B drugs enabled Genesis to enjoy a $19 million surplus over its $52 million in revenue in 2021—a 37% margin. And increases in 340B margins have not been correlated with an increase in charity care. *See* Jonathan Larsen et

al., Temple Univ. Ctr. for Pub. Health L. Rsch., Patient Affordability And Debt Collection Policies At 340B Program Hospitals, at 2 (May 2022) (concluding that few of the 75 340B hospitals surveyed appeared to give direct financial assistance on medicines to low-income patients).

Third, Genesis's definition depends on an untenable relationship between the patient definition and the purpose of the 340B program. In Genesis's view, every individual who once had some encounter of any kind with Genesis, no matter how long ago or how tangential to the patient's current prescription, allows Genesis to claim a discount and profit on that individual's prescription (generating 340B "spread"). As discussed above, that will include individuals with insurance or otherwise with the ability to pay. That, too, conflicts with the aim of the 340B program, which expects covered entities to either "pass all or a significant part of the discount to their patients" or set prices so as to "reach more eligible patients." 61 Fed. Reg. at 43,551. Indeed, HRSA has long evidenced a concern that covered entities distribute 340B drugs only to eligible patients. *See id.* (discussing how covered entities and contractors can verify patient eligibility). Yet it appears that, consistent with its expansive "patient" definition, Genesis distributed 340B drugs to individuals for whom it did not even have medical records. *See* Dkt. 1-3 at 3 (explaining that for eight sampled prescriptions, "[Genesis] did not provide records of the individuals' health care.").

Genesis complains that applying a proper definition of "patient" would put Genesis in a "legal bind" because it "could not assist patients with access to discounted 340B drugs if they obtained a prescription from a non-Genesis provider." Dkt. 100-1 at 19 (arguing also that these individuals would not have access to "patient counseling services"). But that is wrong on all counts. Nothing prevents Genesis from assisting individuals who receive healthcare services from a different provider; Genesis is merely prevented from leveraging that incidental contact for its

own gain. Nor would those individuals face any harm, as they access their medications regardless of Genesis's ability to profit from claiming them as "patients." The primary problem is that Genesis is accessing manufacturers' drugs at deeply discounted prices and then selling them at non-discounted prices to pharmacy customers, who are indifferent to, and likely unaware of, Genesis's ability to purchase 340B drugs at discounted prices. Genesis may wish as a policy matter that the 340B statute did not include its anti-diversion prohibition and the requirement that a 340B eligible individual be a "patient *of the entity*" and not a patient of someone else. *See* 42 U.S.C. § 256b(a)(5)(B) (emphasis added). But that is the statute that Congress enacted. Complying with the statute does not put Genesis in any "legal bind."

Fourth, Genesis's definition creates a serious risk that multiple entities will receive a discount on the same drugs. Genesis asserts that once it provides a healthcare service of any kind to an individual, that individual is forever and always a patient of Genesis for all purposes. Imagine a scenario where Genesis prescribes a diabetes medication to John Doe. One year later, John Doe establishes a relationship with another covered entity for diabetes treatment and is prescribed the same drug. Now, under Genesis's definition, both Genesis and the other covered entity have John Doe in their records as a patient with a diabetes prescription. And both can seek to claim a 340B discount for that drug. So a manufacturer is providing two discounts on the same unit of a drug to two different entities, because both can claim the individual as a patient. Indeed, the same result would occur if John Doe received a prescription for cholesterol from Genesis on Monday and a prescription for glaucoma from another covered entity on Tuesday. Under Genesis's definition, both Genesis and the other covered entity can claim John Doe as a patient and receive a 340B discount for both drugs.

Congress cannot have intended the unfair and illogical result of granting two (or more) entities the right to receive a discount on the exact same unit of a drug. Unless "patient" is interpreted as requiring a clear nexus to specific, ongoing care by a covered entity's physician, there will be no limitation on how many covered entities could claim a 340B discount on one unit of a product.

In short, Genesis seeks to continue and expand its arbitrage scheme by having this Court adopt an overly expansive and indeterminate definition of "patient." That request should be denied because it would further transform 340B from a statute benefiting the needy into an ever-expanding cash cow for covered entities.

B. The Other Relief That Genesis Seeks Is Not Justified or Appropriate.

For the reasons discussed above, this Court should deny Genesis's request for a declaration that "patient of the entity" means "patient of a covered entity" and that, under 42 U.S.C. § 256b(a)(5)(B), "any prescription from any source is available to a patient of a covered entity," Dkt. 100-1 at 7-9, 20. This Court should likewise deny Genesis's request for a stay, which is predicated on its understanding of the term "patient," for the same reasons. *See* Dkt. 33 ¶¶ 52-55. Genesis's next request for relief is for this Court to declare that "any and all interpretations or guidance of HRSA in contradiction of the plain wording of 42 U.S.C. § 256b(a)(5)(B) unlawful and unenforceable as a matter of law." Dkt. 100-1 at 20. Because Genesis incorrectly argues this description applies to any definition of the word "patient" that goes beyond "patient of a covered entity," the Court should also reject this request. *See id.* at 7-9.

That leaves only Genesis's request for a declaration that "HRSA does not have the broad rulemaking authority necessary to implement its interpretations and restrictions to the plain language of 42 U.S.C. § 256b(a)(5)(B)." *Id.* at 10-13, 21. Yet both sides agree that HRSA lacks statutory authority to engage in rulemaking except as specified by statute. *See Pharm. Rsch. &*

Mfrs. of Am., 43 F. Supp. 3d at 43. HRSA has taken that position in judicial filings in other cases. *See* Reply at 8, *Am. Hosp. Ass'n v. HHS*, No. 20-8806, 2021 WL 4243477 (N.D. Cal. Feb. 1, 2021); *see also* Opening Brief at 8, *AstraZeneca Pharms., LP v. Becerra,* No. 22-1676, 2022 WL 2302610 (3rd Cir. June 21, 2022); Principal & Response Brief at 14-15, *Eli Lilly & Co. v. Cochran*, No. 21-3405 (7th Cir. June 24, 2022), Dkt. 37; Principal & Response Brief at 26, *Novo Nordisk Inc. v. HHS,* No. 21-3380, 2022 WL 1553240 (3rd Cir. May 9, 2022); Opening Brief at 12, *Novartis Pharms. Corp. v. Becerra*, No. 21-5299 (D.C. Cir. May 9, 2020); Opening Brief at 7, *United Therapeutics Corp. v. Johnson*, No. 21-5299, 2022 WL 1487100 (D.C. Cir. May 18, 2022). Moreover, HRSA has not purported to exercise rulemaking authority when it issued its 1996 guidelines or any other guidance regarding the patient definition. So whether HRSA may exercise rulemaking authority to change the statutory definition of "patient" is not at issue.

CONCLUSION

This Court should grant summary judgment in favor of defendants and dismiss Genesis's Amended Complaint with prejudice.

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Respectfully submitted,

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